REMARKS

Claims 1, 3-5, 8-10, 16 and 17 are pending. Claims 1, 3-5, 8-10, 16 and 17 are rejected. By virtue of this response, claims 1 and 3-4 have been amended. Accordingly, claims 1, 3-5, 8-10, 16, and 17 are currently under consideration.

Amendments

Claims 1 and 3-4 have been amended. Support for the amendment to claim 1 is found in the specification, *inter alia*, on page 17, lines 19-20. Support for the amendment to claims 3-4 is found in the specification, *inter alia*, on page 17, lines 9-16.

With respect to the amendment to claims, Applicant has not dedicated or abandoned any unclaimed subject matter and, moreover, have not acquiesced to any rejections and/or objections made by the Office. Applicant expressly reserves the right to pursue prosecution of any presently excluded claim embodiments in future continuation, continuation-in-part, and/or divisional applications.

Claims Rejections – 35 U.S.C. § 102

Claims 1, 3, 8-10 and 16 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Wagner *et al.* (U.S. 2004/0030118). Applicant respectfully traverses.

The Examiner alleges that Wagner *et al.* teach a process comprising administration of a composition to the respiratory tract of a subject by local administration, wherein said composition comprises a polynucleotide comprising an ISS comprising the TCG motif. *See* Office Action dated 10/16/08 at page 3.

Applicant respectfully disagrees. However, solely to expedite prosecution and without acquiescing to the Examiner's statement, Applicant has amended claim 1 to recite a "method of suppressing a respiratory syncytial virus (RSV) infection in an individual who is at risk of being exposed to RSV, comprising administering a composition to the respiratory tract of said individual by local administration, said composition comprising a polynucleotide comprising an immunostimulatory sequence (ISS), wherein the ISS comprises the sequence 5'-CGTTCG-3', wherein the polynucleotide is greater than 6 and less than about 50 nucleotides in length, wherein

RSV antigen, an immunostimulatory cytokine, and an adjuvant are not administered in conjunction with administration of said composition, wherein the individual is a human, wherein said composition is administered between 3 days and 14 days before exposure to RSV, and wherein said polynucleotide is administered in an amount sufficient to reduce RSV titer."

It is submitted that Wagner *et al.* does not identically disclose the method recited by amended claim 1.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1, 3, 8-10 and 16 under 35 U.S.C. § 102(e) as allegedly being anticipated by Wagner *et al.*

Claims Rejections – 35 U.S.C. § 103

I. Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Wagner et al. (U.S. 2004/0030118) in view of Raz, E. (U.S. 2003/0092663).

Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Wagner *et al.* (U.S. 2004/0030118), as applied to claims 1 and 3, in view of Raz, E. (U.S. 2003/0092663; "Raz"). Applicant respectfully traverses.

The Examiner alleges that it would have been prima facie obvious for one of ordinary skill in the art to use the polynucleotide of Raz as an alternative to the polynucleotide used by Wagner *et al.*

Applicant respectfully disagrees. Applicant submits claims 1 and 3-5 are not obvious in view of the references cited by the Examiner.

As discussed above, Wagner *et al.* do not teach or suggest an ISS which comprises the sequence 5'-CGTTCG-3'. There is no reasonable expectation of success that the claimed method to suppress RSV infection could be developed using an ISS comprising the sequence 5'-CGTTCG-3'based on the disclosure in this reference.

Further, Wagner *et al.* do not teach or suggest the particular combination of disease, ISS sequence, timing, and site of administration as recited in the claims of the present application. Wagner *et al.* indicate that the methods of their invention are useful for treating cancer, infectious

disease including infectious viruses, infectious bacteria, and infectious fungi, and allergic diseases. *See* Wagner *et al.* at page 7, paragraph [0081] – page 8, paragraph [0089] and page 9, [0095] – page 10, [0098]. Wagner *et al.* describe a long list of conditions that may be treated. Within this long list of unrelated diseases, Wagner *et al.* include a speculative catalog of over 20 families and 50 species of infectious viruses including RSV. *See* Wagner *et al.* at page 7, paragraph [0081]. Further, Wagner *et al.* describe a long list of administration routes that may be used in the treatment of a long list of diseases including oral, transdermal, injection (including parenteral and intravenous), intranasal, intratracheal, and mucosal. However, there is no suggestion or appreciation in Wagner *et al.* that the mechanism of each condition is distinct and the administration route important. As shown in the Applicant's specification in Example 2, local administration of an immunostimulatory sequence (ISS) comprising the sequence 5'-CGTTCG-3' to an individual "was effective at reducing viral titers" for a RSV infection, while non-local administration did not result in a statistically significant reduction of RSV viral titer. *See* page 40, lines 9-10 and Tables 4 and 5. Wagner *et al.* do not provide any teach that would suggest that to suppress an RSV infection, an ISS sequence including an ISS sequence comprising the sequence 5'-CGTTCG-3' must be administered locally.

Applicant notes that

> prior art . . . must sufficiently describe the claimed invention to have placed the public in possession of it. Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention.

In re Donohue, 766 F.2d 531, 533 (Fed. Cir. 1985). Applicant submits that Wagner *et al.* do not sufficiently describe a method of suppressing a respiratory syncytial virus (RSV) infection in an individual who is at risk of being exposed to RSV, comprising administering a composition to the respiratory tract of said individual by local administration, said composition comprising a polynucleotide comprising an immunostimulatory sequence (ISS), wherein RSV antigen, an immunostimulatory cytokine, and an adjuvant are not administered in conjunction with administration of said composition, wherein the individual is a human, wherein said composition is administered between 3 days and 14 days before exposure to RSV, and wherein said polynucleotide is administered in an amount sufficient to reduce RSV titer. There is not sufficient disclosure in

Wagner *et al.* to have placed the public in possession of the specific elements of the method of claim 1.

The deficiency of Wagner *et al.* is not corrected through combination of the disclosure of Raz. Raz discloses ISS sequences but does not teach or suggest that to suppress an RSV infection, an ISS sequence comprising the sequence 5'-CGTTCG-3' is administered locally prior to infection with RSV.

One skilled in the art would not have been motivated to combine the teachings of Wagner *et al.* and Raz and would not have combined these references to arrive at the specific methods for suppressing an RSV infection recited in the amended claims.

In view of the foregoing, Applicant respectfully submits that the Examiner has not established a *prima facie* case of obviousness and requests reconsideration and withdrawal of the rejection of claims 1 and 3-5 under 35 U.S.C. § 103(a).

II. Claims 1 and 17 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Wagner et al. (U.S. 2004/0030118).

Claims 1 and 17 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Wagner *et al.*, as applied to claim 1. Applicant respectfully traverses.

The Examiner alleges that it would have been *prima facie* obvious for one of ordinary skill in the art to include a pharmaceutically acceptable excipient with the composition of Wagner *et al.*

Applicant respectfully submits amended claims 1 and 17 are not obvious over Wagner *et al.* As discussed above, Wagner *et al.* do not teach or suggest a method of suppressing a RSV infection in an individual who is at risk of being exposed to RSV by local administration of an ISS comprises the sequence 5'-CGTTCG-3'.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1 and 17 under 35 U.S.C. § 103(a).

Double Patenting

Applicant notes with appreciation that the Examiner has withdrawn the provisional nonstatutory obviousness-type double patenting rejection of claims 1, 3-5, 8-10 and 16-17 over claims 1-9 of Application No. 10/426,237.

Claims 1, 3-5, 8-10 and 16-17 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 11 of copending Application No. 10/898,512. When the conflicting claims have been found to be allowable, Applicant will address this provisional double patenting rejection with a Terminal Disclaimer.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 377882000900. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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